IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC., PFIZER IRELAND PHARMACEUTICALS, WARNER-LAMBERT COMPANY, WARNER-LAMBERT COMPANY, LLC and WARNER-LAMBERT EXPORT LTD. Plaintiffs, v. RANBAXY LABORATORIES LIMITED, RANBAXY PHARMACEUTICALS, INC. and RANBAXY INC Defendants.	C. A. No. 08-164-JJF **REDACTED VERSION**

OPENING BRIEF IN SUPPORT OF RANBAXY'S MOTION TO DISMISS PLAINTIFFS' COMPLAINT

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page Nos.

TABLE OF AUTHORITIES
(*cont'd*)

Page Nos.

OTHER AUTHORITIES

Defendants Ranbaxy Laboratories Limited, Ranbaxy Pharmaceuticals Inc and Ranbaxy Inc. (collectively, "Ranbaxy") hereby submit this Opening Brief in Support of their Motion to Dismiss Plaintiffs' Complaint for Lack of Subject Matter Jurisdiction. This Motion is supported by the Declaration of Jay R. Deshmukh, Esq., submitted herewith.

I. INTRODUCTION

On March 24, 2008, Plaintiffs Pfizer Inc., Pfizer Ireland Pharmaceuticals, Warner-Lambert Company, Warner-Lambert Company, LLC and Warner-Lambert Export Ltd. (collectively, "Pfizer") filed two separate Complaints against Ranbaxy regarding U.S. Patent Nos. 6,087,511 (the "'511 patent") and 6,274,740 (the "'740 patent"), which relate solely to *processes* for making certain atorvastatin compounds. These Complaints, *inter alia*, seek to enjoin approval of Ranbaxy's Abbreviated New Drug Applications ("ANDAs") for generic versions of Pfizer's Caduet® and Lipitor® products, respectively, both of which contain atorvastatin.[1]

Pfizer's Complaints allege that Ranbaxy "intends" to engage in future acts that "will" infringe the '511 and '740 patents (Complaints ¶¶ 29, 31.) But the alleged acts cannot possibly result in the actual or imminent injury to Pfizer required to establish subject matter jurisdiction. Moreover, Pfizer will not face any hardship, if ever, until

[1] The present action, C.A. No. 08-164 (JJF), relates to Ranbaxy's ANDA for a generic version of Lipitor® (No. 76-477). The co-pending action, C.A. No. 08-162 (JJF), relates to Ranbaxy's ANDA for a generic version of Caduet® (No. 78-747). Because Pfizer's Complaints in those actions are almost identical, and the facts supporting Ranbaxy's Motions to dismiss each Complaint are largely the same, Ranbaxy addresses both Complaints in this brief, and has simultaneously filed an identical brief (with the exception of this footnote) in the co-pending action.

such time as it could allege conduct that goes beyond hypothetical speculation and rises to the level of concrete reality

Indeed, Ranbaxy is currently enjoined by two separate Court orders from marketing any atorvastatin product, whether in the form of generic Lipitor® or Caduet®, until March 2010.

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With no actual or imminent harm to Pfizer, REDACTED

REDACTED Pfizer cannot possibly meet its burden to demonstrate a justiciable, Article III case or controversy. As such, the Court should dismiss Pfizer's Complaints in their entirety.

II. BACKGROUND FACTS

Pfizer's Complaints mark the third and fourth time, respectively, that Pfizer has sued Ranbaxy based on Ranbaxy's efforts to market drug products containing atorvastatin. When Ranbaxy first sought FDA approval to market a generic version of Lipitor®, a drug product that includes atorvastatin calcium, it certified to Pfizer in 2003 that it did not infringe any valid patent that Pfizer, as required by law, had listed in the FDA's Orange Book with respect to Lipitor®. Pfizer did not agree, and sued Ranbaxy in this Court for patent infringement on two patents relating to the compound atorvastatin calcium, U.S. Patent Nos. 4,681,893 and 5,273,995 (the "'893 and '995 patents," respectively). (*See* Civ. Action No. 03-209-JJF (Consolidated) (the "Lipitor case").)

During the Lipitor case, Pfizer moved for leave to amend its pleadings to add new patent infringement claims based on the '511 and '740 process patents. (Lipitor case, D.I. 41.) Pfizer thus sought to broaden its lawsuit to focus not only on the compound atorvastatin calcium, but also on *processes* for making atorvastatin calcium implicated by the '511 and '740 patents. As in the present actions, the patent infringement allegations Pfizer sought to add were based on 35 U.S.C. § 271(g), asserting that Ranbaxy intends to use, sell, offer to sell or import a product made by a process which, if practiced in the United States, would infringe processes claimed in the '511 and '740 patents. (Lipitor case, D.I. 42.) Although Ranbaxy had not engaged in any of those acts, Pfizer argued that a patentee may seek a declaration of future infringement and that the Court would have jurisdiction over the new counts under the Declaratory Judgment Act. (*Id.* at 6-11.)

Ranbaxy opposed Pfizer's Motion to add these process patent claims, arguing that Pfizer had not made a sufficient allegation of immediacy and reality to establish the existence of an actual controversy. (Lipitor case, D.I. 44.)

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Ranbaxy argued that Pfizer thus had no basis for any prediction as to when Ranbaxy might ever engage in any act of using, selling, offering to sell or importing an atorvastatin calcium-based product in the United States. (*Id.* at 9.)

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The Court agreed with Ranbaxy, stating that "because of the uncertainty surrounding Ranbaxy ANDA efforts, Pfizer's attempt to join claims under its '511 and '740 patents by invoking the Declaratory Judgment Act, 28 U.S.C. § 2201, are premature." (Lipitor case, D.I. 139.) The Court further found that "waiting for any claims involving Ranbaxy's manufacturing process to mature so that such claims comport with the immediacy and reality standard will not prejudice Pfizer in any way." (*Id.*)

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In January 2006, the Court entered a Final Judgment in the Lipitor case. (Lipitor case, D.I. 331.) The Final Judgment Order enjoins Ranbaxy as follows:

> ORDERED that pursuant to 35 U.S.C. § 271(e)(4)(B), defendants Ranbaxy Laboratories Limited and Ranbaxy Pharmaceuticals Incorporated, each of their officers, agents, servants, employees and attorneys, and those persons in active concert or participation with them or either of them are permanently enjoined from engaging in the manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any product comprising atorvastatin calcium covered by, or the use of which is covered by claims 1-4 and 8-9 of the '893 Patent . . . .

(*Id.* ¶ 7.) Pursuant to 35 U.S.C. § 271(e)(4)(A), the Lipitor injunction further prohibits the FDA from approving Ranbaxy's Lipitor® ANDA until the '893 patent expires on March 24, 2010. (*Id.* ¶ 5.)

Thus, in accordance with the Lipitor injunction, Ranbaxy cannot engage in using, selling, offering to sell or importing into the United States any product that includes atorvastatin calcium until at least March 24, 2010. (*Id.*) The Lipitor injunction thus prohibits Ranbaxy from engaging in the very conduct that Pfizer now alleges gives rise to

the two counts of patent infringement. As a result, no harm to Pfizer resulting from such conduct could possibly be imminent.

A similar injunction against Ranbaxy is also in place in a case currently pending before this Court concerning Ranbaxy's ANDA for a generic version of Caduet®, a product which combines atorvastatin calcium with another well-known commercial drug, amlodipine besylate. (*See* C.A. 07-138 (JJF) (the "Caduet case").) On December 13, 2007, based on the injunction in the Lipitor case, this Court entered a Stipulated Amended Order of Final Judgment in the Caduet case enjoining Ranbaxy from selling any product comprising atorvastatin calcium and amlodipine besylate covered by the '893 patent. (Caduet case, D.I. 50 ¶ 8.) Pursuant to 35 U.S.C. § 271(e)(4)(A), the Caduet injunction further prohibits the FDA from approving Ranbaxy's Caduet® ANDA until the '893 patent expires on March 24, 2010. (*Id.* ¶ 7.)

Certainly, the Lipitor and Caduet injunctions make any harm to Pfizer from alleged infringement of the '511 and '740 patents *much less* imminent now than in the Lipitor case when the Court found no imminent threat of harm or injury. Indeed, Pfizer did not assert the '511 and '740 patents against Ranbaxy when it recently filed the Caduet case in 2007, and nothing has happened in the interim that could possibly give rise to an actual or imminent threat of harm to Pfizer.

Aside from the Lipitor and Caduet injunctions, any time frame for final FDA approval of Ranbaxy's ANDA products remains uncertain.[2]

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[2] The FDA cannot grant final approval for either of Ranbaxy's ANDAs until: (1) it reviews the ANDAs and grants a tentative approval, and (2) this Court's injunctions prohibiting FDA approval lapse.

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III. ARGUMENT

A. DECLARATORY JUDGMENT JURISDICTION REQUIRES AN ARTICLE III CASE OR CONTROVERSY

Dismissal of a declaratory judgment action for lack of jurisdiction is a question of law, as is the determination of whether an actual controversy exists under the Declaratory

Judgment Act *See Caraco Pharm Labs Ltd v Forest Labs, Inc*, No 2007-1404, 2008 WL 850330 at *8 (Fed Cir Apr 1, 2008); *Teva Pharms USA, Inc v Novartis Pharms Corp*, 482 F3d 1330, 1335-36 (Fed Cir 2007) As the party claiming jurisdiction under the Declaratory Judgment Act, Pfizer bears the burden to establish that such jurisdiction existed at the time it filed its Complaints and that jurisdiction has continued since that time *See Benitec Australia, Ltd v Nucleonics, Inc*, 495 F3d 1340, 1344 (Fed Cir), *cert denied*, 2008 WL 1775071 (Apr 21, 2008)

The relevant text of the Declaratory Judgment Act provides:

> In a case of actual controversy within its jurisdiction . . . any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought

28 U S C § 2201(a)

The Supreme Court, in *MedImmune, Inc v Genentech, Inc*, 549 U S 118, 127 S Ct 764 (2007), confirmed that the Act refers to cases and controversies that are justiciable under Article III In accordance with its earlier decisions, the Court reaffirmed that for jurisdiction to exist:

> [T]he dispute be definite and concrete, touching the legal relations of parties having adverse interests; and that it be real and substantial and admi[t] of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts . . . Basically, the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between the parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment

Id at 771 (internal quotations and citations omitted)

In applying this guidance, the Federal Circuit has stated that "in a declaratory judgment action, 'all the circumstances' must demonstrate that a justiciable Article III

'controversy' exists." *Teva*, 482 F.3d at 1337. In particular, a declaratory judgment plaintiff must "satisfy Article III, which includes standing and ripeness, by showing under 'all the circumstances' an actual or imminent injury caused by the defendant that can be redressed by judicial relief and that is of 'sufficient immediacy and reality to warrant the issuance of a declaratory judgment.'" *Id.* at 1338 (citing *MedImmune*, 127 S. Ct. at 771).

Following *MedImmune*, the Federal Circuit has tested the existence of jurisdiction in declaratory judgment actions by scrutinizing the traditional justiciability factors of standing and ripeness to determine whether a controversy of sufficient immediacy and reality exists. *See Caraco*, 2008 WL 850330, at *9 (observing that a declaratory judgment action is justiciable under Article III only where the plaintiff has standing and the issues presented are ripe for judicial review); *Teva*, 482 F.3d at 1340 (examining standing and ripeness to determine whether a justiciable controversy existed within Article III).[3]

In *Caraco*, the Federal Circuit applied the "Supreme Court's three-part framework" for determining whether a declaratory judgment action presents a justiciable Article III controversy. *Caraco*, 2008 WL 850330, at *9. In particular, an action is justiciable under that framework only if (1) the plaintiff has standing, (2) the issues presented are ripe for judicial review, and (3) the case is not rendered moot at any stage

[3] The Third Circuit similarly analyzes standing and ripeness when deciding declaratory judgment jurisdiction. *See PA. Family Inst. v. Black*, 489 F.3d 156, 165 (3d Cir. 2007) (affirming a district court's dismissal of an action for declaratory and injunctive relief in an appeal argued just before the Supreme Court issued *MedImmune*).

of the litigation. *Id.*; *see also Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61, 112 S. Ct. 2130 (1992); *Abbott Labs. v. Gardner*, 387 U.S. 136, 149 (1967).

On the present record, Pfizer cannot meet its burden to establish the existence of a justiciable case or controversy under Article III.

B. NO ARTICLE III CASE OR CONTROVERSY EXISTS

Because Pfizer has failed to allege any imminent injury traceable to any conduct by Ranbaxy, Pfizer cannot meet its burden to establish the constitutional minimum of standing. Nor can Pfizer show that the two infringement counts in its Complaints are ripe for judicial review. Finally, if any mootness analysis were applicable here, evolving facts may moot these actions. Thus, as explained in more detail below, the Court should dismiss Pfizer's Complaints for lack of an Article III justiciable case or controversy.

1. STANDING DOES NOT EXIST

The Supreme Court's requirements for standing are well-settled. The "irreducible constitutional minimum of standing" contains three requirements: (1) the party claiming jurisdiction must allege an injury-in-fact that is concrete and actual or imminent and not conjectural or hypothetical; (2) the injury must be traceable to the complained-of conduct of the defendant; and (3) it must be likely that the requested relief will redress the alleged injury. *See Lujan*, 504 U.S. at 560-61 (1992); *see also Caraco*, 2008 WL 850330, at *9 (applying the three requirements to assess standing in a declaratory judgment action). Of the three standing requirements, "injury-in-fact is the most determinative" and indeed is the "essence" of an Article III case or controversy. *Teva*, 482 F.3d at 1337 (citing *Schlesinger v. Reservists Comm. to Stop the War*, 418 U.S. 208, 218 (1974)).

On the critical injury-in-fact requirement, Pfizer can make no showing whatsoever. Pfizer's only allegation of injury is that it "will be" harmed if Ranbaxy is not enjoined from infringing the '511 and '740 patents (Complaints ¶¶ 32, 43.) Nowhere does Pfizer allege that it "has been" or "is being" harmed in any way. Thus, as is plainly apparent from the face of the Complaints, Pfizer's action concerns no concrete or actual injury.

As is also plain from the Complaints, any alleged harm to Pfizer could only arise if Ranbaxy imports, offers to sell, sells or uses in the United States a product that includes atorvastatin calcium. (Complaints ¶¶ 24, 29-32, 35, 40-43.) Importantly, as a result of the Lipitor and Caduet injunctions, this Court has already enjoined Ranbaxy from engaging in precisely that conduct. (Lipitor case, D.I. 331; Caduet Case, D.I 50.) Those injunctions will continue until March of 2010. (*Id.*) Because Pfizer has alleged no harm that could possibly arise from any conduct other than that already enjoined well into 2010, Pfizer has failed to allege imminent injury. This fundamental failure, alone, demonstrates a lack of standing and a consequent lack of subject matter jurisdiction. *See Benitec*, 495 F.3d at 1346 (anticipated infringing activity by 2010 did not present a controversy of sufficient immediacy and reality to warrant declaratory judgment jurisdiction)

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Finally, according to Pfizer's allegations, injury could arise only if Ranbaxy imports, offers to sell, sells or uses in the United States a product that includes atorvastatin calcium *made by the processes* claimed in the '511 and '740 patents. (Complaints ¶¶ 24, 29-32, 35, 40-43.) REDACTED

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In sum, the "injury" that Pfizer has alleged is one that could arise only from conduct that (1) has already been enjoined by this Court

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Nothing about such injury could be imminent. Therefore, the "most determinative" aspect of standing — injury-in-fact — cannot be established by Pfizer.

2. RIPENESS DOES NOT EXIST

Whether Pfizer's action is ripe requires evaluation of "both the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration." *Caraco*, 2008 WL 850330, at *12 (citing *Abbott Labs.*, 387 U.S. at 149). Considering the first prong, an action is fit for judicial review where further factual development would not significantly advance the court's ability to address the issues presented. *See Nat'l Park Hospitality Ass'n v. Dept. of Interior*, 538 U.S. 803, 812 (2003). As for the second prong, withholding court consideration causes hardship to the plaintiff where the complained-of conduct has an "immediate and substantial impact" on

the plaintiff. *Gardner v. Toilet Goods Ass'n*, 387 U.S. 167, 170-71 (1967). Both prongs of the ripeness inquiry show that Pfizer's action is not ripe.

First, Pfizer's action is not fit for judicial review. Pfizer's Complaints allege that each of the '511 and '740 patents covers a method of making atorvastatin. (Complaints ¶¶ 28, 39.) Pfizer alleges that Ranbaxy would use the methods of those patents to make atorvastatin. (*Id.* ¶¶ 30, 41.)

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Accordingly, the first prong of the ripeness inquiry shows that Pfizer's action is not ripe.

The second prong of the ripeness inquiry — the evaluation of hardship — confirms the same. As explained in detail above, no complained-of conduct by Ranbaxy is having any "substantial and immediate" impact on Pfizer. Indeed, Ranbaxy stands enjoined from engaging in the complained-of conduct

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Thus, withholding consideration of this action will not cause any hardship to Pfizer, much less the "substantial and immediate" hardship that ripeness requires

Pfizer's action seeks no more than an advisory ruling based on uncertain and evolving conduct that is causing Pfizer no hardship whatsoever. Pfizer's action fails both of the required prongs of the ripeness inquiry. Accordingly, the Court should dismiss Pfizer's action for failing to present a justiciable Article III controversy. *See NeoRx Corp. v. Immunomedics, Inc.*, 877 F. Supp. 202 (D.N.J. 1994) (declaratory judgment action not ripe for adjudication because device was not approved by FDA and because it was not uncommon for devices to be modified during clinical testing); *see Intermedics, Inc. v. Ventritex, Inc.*, 775 F. Supp. 1269, 1290 (N.D. Cal. 1991), *aff'd*, 991 F.2d 808 (Fed. Cir. 1993) (motion to dismiss plaintiff's declaratory relief claims for patent infringement granted because FDA approval had not been given, because there was no basis to determine when it would be given and because defendants might make changes to the device as a condition of approval.).

3. **EVOLVING FACTS MAY MOOT THIS ACTION**

Because mootness assumes that standing and ripeness must first exist, the question of mootness need not be addressed here.

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C. THE COURT SHOULD EXERCISE ITS DISCRETION TO DECLINE JURISDICTION

Even if this Court were to determine that is has subject matter jurisdiction, it is within the Court's discretion to decline to exercise such jurisdiction. *See Telectronics Pacing Sys., Inc. v. Ventritex, Inc.*, 982 F.2d 1520, 1526-27 (Fed. Cir. 1992). Given the current injunction barring Ranbaxy from bringing to market any atorvastatin products,

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this Court should exercise its discretion to decline jurisdiction and dismiss both of Pfizer's Complaints.

Such exercise of discretion would be consistent with the Congressional intent behind the ANDA statutes. Under those statutes, submission of an ANDA may be deemed an "artificial" act of infringement, but only with respect to patents that claim a "drug" or "the use" of such drug. 35 U.S.C. § 271(e)(2); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990). Congress specifically excluded from the scope of 35 U.S.C. § 271(e)(2) patents that claim manufacturing methods. Congress never intended that process patents would be included in ANDA-stage patent litigation. Indeed, while Congress established a statutory framework that allows a patentee to sue on product and method of use patent claims based solely on the filing of an ANDA (i.e., well before product approval and launch), Congress chose not to include process patents in this framework. Pfizer should not be permitted to circumvent Congress's jurisdictional

framework. Because, as Pfizer admits, the '511 and '740 patents cover only methods of manufacturing, § 271(e)(2) provides no basis for jurisdiction in this action, despite the filing of Ranbaxy's ANDAs seeking FDA approval for an atorvastatin calcium-based product.

IV. CONCLUSION

For the foregoing reasons, Ranbaxy respectfully requests that the Court dismiss Pfizer's Complaints alleging infringement of the '511 and '740 patents by Ranbaxy ANDA Nos. 76-477 and 78-747.

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Dated: April 24, 2008

UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on May 1, 2008, I electronically filed the foregoing with the Clerk of Court using CM/ECF and caused the same to be served on the plaintiff at the addresses and in the manner indicated below:

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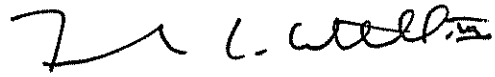

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